

**REMARKS**

Claims 1-23, 25-30 and 32-40 are pending and have been rejected by the Examiner over prior art. New claims 41 and 42 are introduced herein.

Before addressing the Examiner's rejections in turn, we should briefly note that independent claims 1 and 13 are directed to a novel method and device for utilizing immobilized specific binding reagent effective for detection of Bence Jones Protein in uncentrifuged urine.

*I) Claims 1-8, 10-21, 23, 25-29, 32, 39 and 40 have been rejected under 35 U.S.C. 103(a) as being unpatentable over of Great British Patent No. 2,204,398 to May (hereinafter "May") in view of U.S. Patent No. 5,141,877 to Massaro (hereinafter "Massaro").*

Claims 1 and 13 have been amended to further clarify the inventive aspects of the applicant's method and device, specifically use of immobilized specific binding reagent effective for detection of Bence Jones Protein in uncentrifuged urine.

As noted by the Examiner, May does not teach such limitations, but rather teaches generally use of labelled specific binding reagents and antibodies to detect analytes on a porous carrier (e.g., for pregnancy tests), but nowhere teaches or suggests detection of Bence Jones Protein, uncentrifuged or otherwise.

Massaro discloses two prior art methods for detecting Bence Jones Protein in urine. Specifically, Massaro discloses turbidity reactions for unconcentrated urine and electrophoretic examination of concentrated urine. Massaro actively teaches away from electrophoretic examination (or similar, i.e., using porous membranes) of anything but concentrated urine. The Examiner is, in the face of this clear lack of desire/motivation to

combine Massaro and May, urging such combination (indeed, it is also noted that Massaro is at least contemporary with May and was actually almost a year after May).

In order to make out a *prima facie* case of obviousness, a proposed combination of prior art references (or indeed in this case, the one utilized reference) must teach or suggest all of the limitations of the rejected claims. *In re Vaech*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991); *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 U.S.P.Q. 494, 496 (CCPA 1970).

The Examiner also cannot use the Applicant's own disclosure as a roadmap for combining the teachings of particular references. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not be based on the Applicant's disclosure. *In re Vaech*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

In the face of the clear lack of motivation to combine the references, as noted above with regard to Massaro's teachings, the proposed combination is improper. It is also clear that the Examiner, by attempting to force the combination, is impermissibly using the applicant's disclosure as a roadmap for the combination. Reconsideration and withdrawal of the rejection is respectfully requested.

II) *Claims 9, 22 and 30 have been rejected under 35 U.S.C. 103(a) as being unpatentable over May in view of Massaro and further in view of U.S. Patent No. 5,807,752 to Brizgy et al. (hereinafter "Brizgy").*

The Examiner uses Brizgy against the teachings certain of the dependent claims (it is noted that dependent claim 30 is now cancelled) that Protein A may be used as an

immobilizing specific binding partner. However, as noted previously, Brizgy does not make up for the deficiencies of May and Massaro with regard to claims 1 and 13, specifically with regard to immobilized specific binding reagent effective for detection of Bence Jones Protein in uncentrifuged urine.

Because the proposed combination does not teach all of the limitations of claims 9 or 22, a prima facie case is not made out. Reconsideration and withdrawal of the rejection is respectfully requested.

*III) Claims 33-38 have been rejected under 35 U.S.C. 103(a) as being unpatentable over May in view of Massaro and further in view of U.S. Patent No. 4,094,647 to Deutsch et al. (hereinafter "Deutsch").*

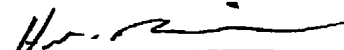
Claim 33 and its dependents (note claims 36-38 have been cancelled) further modify claim 13 by also requiring a reaction tube for mixing said test strip with an aliquot of uncentrifuged urine. Deutsch simply teaches use of a test tube to contain a strip and urine or other sample. Deutsch does nothing to add to May or Massaro with regard to the instant invention (specifically, use of immobilized specific binding reagent effective for detection of Bence Jones Protein in uncentrifuged urine).

Because the proposed combination does not teach all of the limitations of claim 33 or its dependent claims, a prima facie case is not made out. Reconsideration and withdrawal of the rejection is respectfully requested.

Allowance of the claims is respectfully requested. If there are any charges with respect to this election or otherwise, please charge them to Deposit Account 06-1130, maintained by Applicant's attorneys.

Respectfully Submitted,

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